

REMARKS

Applicant thanks the Examiner for entering and considering Applicant's previous submissions. Applicant thanks the Examiner for withdrawal of a number of previous rejections in light of Applicant's previous submission.

Claims 23, 25, 27-29, 31-33, 35, 37-39, 69-71, 73-80, 82, 84-90 and 95-97 were pending in the application, with Claims 23, 27, 29, 31-33, 37-39, 76, 80, 82, 84 and 95-97 rejected in the current Office Action.

In the present response, Claim 76 and its dependent claims 84 and 97 have been cancelled, without prejudice. Independent Claims 23 and 33 have been amended. As the remaining claims depend ultimately either from claim 23 or 33, the remaining claims incorporate these amendments. Accordingly, presently Claims 23, 25, 27-29, 31-33, 35, 37-39, 69-71, 73-75, 77-80, 82, 85-90 and 95-96 are pending, with pending amended Claims 23, 27, 29, 31-33, 37-39, 80, 82 and 95-96 under examination.

Regarding section 11 of the Office Action, Claim 76 was rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1, 4, 6 and 7 of US patent 7,910,548. The rejection is mooted by cancellation of Claim 76. Claims 84 and 97, previously dependent on claim 76, are also cancelled. Withdrawal of the rejection is requested.

Regarding section 12 of the Office Action, Claims 23 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of the US patent 5,686,411 issued to Gaeta et al. (of record) as evidenced by Tsanev (Vutr.Boles 23: 12-17, 1984, abstract, of record). It was asserted that while the conflicting claims are not identical, they are not patentably distinct from each other, in view of the method claimed in claim 31 of the US patent 5,686,411 for the treatment of diabetes mellitus in a mammal comprising the administration to said mammal of a therapeutically effective amount of the amylin agonist analogue of claim 6, i.e., an amylin agonist analogue of instantly recited SEQ

ID NO: 14, and would include a human, and in view of the Tsanev disclosure. Without acquiescing to the rationale of the present invention, Claims 23 and 33 have been amended to recite that their compositions “consists essentially of” the recited amylin agonist analogue. Claims 23 and 33 were also amended to recite that body weight is reduced by said treatment. Accordingly, the claims as amended are believed to address the issue raised by the Examiner, distinguish over the claims of the cited reference, and at the time would not have been suggested from the claims of the cited reference. As claims 80 and 82 depend from 23 and 33, respectively, they incorporate the limitations of the independent claims and are thus also so distinguished and believed distinct and non-obvious over the claims of the cited patent. Withdrawal of the rejection is requested.

Regarding section 13 of the Office Action, Claim 76 was rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 34 and 35 of the US patent 5,686,411 issued to Gaeta et al. (of record) as evidenced by Tsanev (Vutr.Boles 23: 12-17, 1984, abstract, of record). Without acquiescing to the rationale of the rejection, the rejection is rendered moot by cancellation of Claim 76. Withdrawal of the rejection is requested.

Regarding section 17 of the Office Action, Claims 23, 27, 29, 31-33, 37-39, 80, 82, 95 and 96 were rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically Claim 23 was viewed as vague and indefinite for lacking proper antecedent basis in the limitation: “the amylin or amylin agonist” at lines 3 and 4. Claim 23 has been amended to correct this oversight. Claim 33 was viewed as vague and indefinite in the limitation: “said amylin or amylin agonist” at lines 4 and 5. Claim 33 has been amended to correct this oversight. Claims 80 and 82 were rejected for the same limitation. Claims 80 and 82 have been amended to correct this oversight. Claims 27, 29, 31, 32, 37-39, 80, 82, 95 and 96, which depend from claim 23 or 33, were also rejected as being indefinite because of their dependence on the indefinite base claim. As the base claims have been amended and are believed to conform to 35 U.S.C § 112, second paragraph, their dependent claims conform as well. Withdrawal of this rejection is requested.

Regarding section 19 of the Office Action, Claims 76, 84 and 97 are rejected under 35 U.S.C § 102(b) as being anticipated by Kolterman et al. (Diabetologia 39: 492-499, April, 1996, of record) (Kolterman et al., 1996) as evidenced by Itasaka et al. (Psychiatr. Clin. Neurosci.54: 340-341, June 2000, of record). Without acquiescing to the rationale of the rejection, the rejection of Claims 76, 84 and 97 is mooted by cancellation of claim 76 and its dependent claims 84 and 97. Withdrawal of the rejection is requested.

Regarding section 20 of the Office Action, Claims 76 and 84 were rejected under 35 U.S.C § 102(a) as being anticipated by Kolterman et al. (WO 96/40220, of record) ('220) as evidenced by Tsanev (Vutr. Boles 23: 12-17, 1984, abstract, of record). Without acquiescing to the rationale of the rejection, the rejection of Claims 76 and 84 is mooted by cancellation of claims 76 and 84. Withdrawal of the rejection is requested.

Regarding section 21 of the Office Action, Claims 23, 33, 80 and 82 were rejected under 35 U.S.C § 102(e)(2) as being anticipated by Gaeta et al. (US 5,686,411, of record) ('411) as evidenced by Tsanev (Vutr. Boles 23: 12-17, 1984, abstract, of record). In the Office Action it was viewed that the limitation “is not administered in conjunction with another obesity relief agent” in claim 23 (and presumably 33) did “not exclude the presence of an anti-diabetic agent, insulin, glucagon, a gastric emptying-inhibiting agent etc. in the recited composition,” and thus was allegedly anticipated by the cited references. Without acquiescing to the rationale of the present invention, Claims 23 and 33 have been amended to recite that their compositions “consists essentially of” the recited amylin agonist analogue. Claims 23 and 33 were also amended to recite that body weight is reduced by said treatment. Accordingly, the claims as amended address the key concern raised by the Examiner, distinguish over the cited references and address the basis for the lack of novelty over the cited references. As claims 80 and 82 depend from 23 and 33, respectively, they incorporate the limitations of the independent claims and are thus also so distinguished. Withdrawal of the rejection is requested.

Applicant requests clarification whether claims 27 and 37 were believed novel by the Examiner over the cited references in the above rejection.

Regarding section 22 of the Office Action, Claims 76 and 84 are rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Gaeta et al. (US 5,686,411, of record) ('411) as evidenced by Tsanev (Vutr. Boles 23: 12-17, 1984, abstract, of record). Without acquiescing to the rationale of the rejection, the rejection of Claims 76 and 84 is mooted by cancellation of claim 76. Its dependent claim 84 has been amended to depend from claim 23 that does not recite^{25,28,29}Pro-h-amylin, and thus cannot be anticipated by the cited references. Withdrawal of the rejection is requested.

Regarding section 15 of the Office Action, Claims 23, 27, 29, 31-33, 37-39, 76, 80, 82, 84 and 95-97 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter allegedly not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. With respect to claims 76, 84 and 97, the rejection is moot in view of cancellation of those claims. In brief, the Office Action alleges that although pramlintide at specific doses and via specific routes was shown to reduce body weight of a specific human population in need of treatment, the specification nor the art at the time shows that the amylin agonist analogues or peptide variants having a structure considerably different from that of pramlintide and falling within the scope of the SEQ ID NO: 14 genus, do retain the obesity-relieving biologic function(s).

The present application is not about nor is it claiming new amylin agonist analogue peptides. Rather it is about a new use for known peptides that act as amylin agonists. In fact the USPTO has already recognized these peptides as amylin agonists in the cited granted Gaeta US 5,686,411 patent of record. The Applicant was the first to discover and demonstrate that an amylin agonist analogue has the function to reduce body weight in a human, and was thus useful to treat obesity. This was first reported with pramlintide, an amylin agonist analogue. Subsequently this activity has been reported to occur with native amylin as demonstrated in Applicant's previous submissions, most notably the reference to Mack *et al.* 2003, of record, teaching that rat amylin administered chronically also provided body weight loss in obese subjects. That the actions of amylin occur via activation of amylin receptor is stated in the

specification, and includes the now claimed amylin action to reduce body weight for treating obesity. As already noted, and as recognized in the Office Action, the specification teaches that amylin agonist peptides falling within the scope of the present claims do indeed have various amylin activities. Thus it is credible that the compounds would also have the amylin activity of reducing body weight. Mack et al. 2003 supports this. There is no factual information of record to believe otherwise at the time of the invention. Thus the specification's teaching regarding this new use of amylin agonist compounds other than pramlintide that was used in the specification's Examples are credible. Unsupported speculations about "obesity genes", gastric emptying controversies, and peptide solubility are not reasonable rejections according to patent law and practice. For example, even if a claimed peptide had lower solubility, even poor solubility, compared to pramlintide, there is no reason established of record to believe that this would exclude the peptide from use in the claimed invention as speculated in the Office Action. To the contrary, at the time the invention was filed, insulin was an effective therapeutic as a suspension. Methods of formulation and delivery are taught in the specification, providing sufficient guidance to exploit the compounds claimed. Regarding the statement in the Office Action regarding gastric emptying controversies, the Applicant has not found the referenced "Applicants' response filed 09/02/04" and would appreciate if the Examiner would provide a copy by fax or email to the undersigned. However, a review of the record indicates that the Applicant has not made contradictory statements. Applicant has not made any statement that the claimed effect relies on gastric emptying activity, and the previous responses highlighting controversies over whether gastric emptying relates to treating obesity are valid and do not provide admission or any basis supporting speculations for the alleged non-enablement of the present claims. The point of the previous submissions is that the compounds recited in the present claim are amylin agonists, and as such will provide the weight loss effect first demonstrated with pramlintide—another known amylin agonist. As already noted in the record, the present genus is a relatively tight one, comprised primarily of chemically conservative changes or exemplified and tested changes, including various known means to mimic a rigid disulfide bond. As already well described in the record, the specification provides describes how to make and how to use the amylin agonist peptides, describes means to formulate, and means to administer, and identifies patients recognized as amenable to such treatment. Applicant respectfully submits that it cannot be reasonably asserted that the claimed invention would

require undue experimentation to practice the invention across the scope of claims. Accordingly, it is credible that the present claims as amended are enabled by the specification. Withdrawal of this rejection is respectfully requested.

Conclusion

Applicant believes that all issues raised in the Office Action have been properly addressed in this response. Accordingly, Applicant respectfully requests entry of the amendments to the claims presented herein, and allowance of the instant Claims. If there are any issues remaining, or if the Examiner has any questions, the Examiner is invited to call the undersigned directly at 858-754-7544 so that the issues can be addressed promptly.

Fees totaling \$130.00 are believed due with this submission. However, if this calculation is incorrect, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535, referencing Docket No. 235/013US. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

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